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Department of
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Minutes

Agricultural Biotechnology Research Advisory Committee

April 23-24, 1990



U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
MINUTES OF MEETING

April 23-24, 1990

TIME, PLACE, AND PARTICIPANTS

The seventh meeting of the Agricultural Biotechnology Research Advisory Committee (ABRAC) took place on April 23-24, 1990, in the Clark Room, Capitol Holiday Inn, 550 C Street S.W., Washington, DC. The meeting was open to the public.

Members present included:

Bennie Osburn, Chair, University of California, Davis, CA;
Ann Sorensen, American Farm Bureau Federation, Park Ridge, IL
Deborah Letourneau, University of California, Santa Cruz, CA
Frank Whitmore, Ohio State University, Wooster, OH;
Sue Tolin, Virginia Polytechnic Institute and State University,
Blacksburg VA;
Edward Korwek, Hogan and Hartson, Washington, DC;
David Andow, University of Minnesota, St. Paul, MN;
Anne Vidaver, University of Nebraska, Lincoln, NE;
David Kline, Iowa State University, Ames, IA;
Alvin Young, Executive Secretary and Director, USDA Office of
Agricultural Biotechnology, Washington, DC.

Three individuals present had been nominated for ABRAC membership, but not yet appointed by the Secretary.
They were:

Richard Witter, Agricultural Research Service, East Lansing, MI;
Lee Bulla, University of Wyoming, Laramie, WY;
Robert Fraley, Monsanto Company, St. Louis, MO.

USDA Office of Agricultural Biotechnology (OAB) staff present included: Daniel Jones, John Gerber, Maryln Cordle, Marshall Phillips, William Robinson, Paul Stern, Marti Asner, Elsie Brown, and Arlene Lyles.

CALL TO ORDER, APPROVAL OF AGENDA AND MINUTES

Dr. Osburn called the meeting to order at 9:09 a.m. He welcomed members, nominees, and others to the meeting and requested that all visitors and observers register at the table where the agendas and other information were placed.

Dr. Osburn asked if there were changes or additions to the proposed agenda. Dr. Young clarified that the staff reports on the agenda would include updates on the status of the proposal for placing transgenic fish in outdoor ponds and on the status

of the brucellosis proposal. No other changes or additions were expressed and the agenda was approved as distributed.

Dr. Osburn turned the attention of the Committee to the minutes of the previous meeting. Corrections were suggested by several members and Dr. Tolin stated that she would submit minor corrections to OAB later.

Dr. Young asked that the minutes reflect that the Guidelines Working Group minutes of February had been completed and transmitted to Dr. Tolin for review and final editing.

INTRODUCTION OF NEW MEMBERS

Dr. Osburn introduced the new Committee members, the past Committee members who had been reappointed, the past alternates who had been appointed to membership, and the individuals who had been nominated for Committee membership, but not yet appointed.

Dr. Young explained that the nominees who have not yet been appointed were invited to participate fully in the discussions and other business of the Committee, but as "members without portfolio", they will not be able to vote on motions before the Committee.

REPORT ON CLEMSON/MONSANTO FIELD TEST

Dr. Osburn noted that there is a critical need to establish how the research guidelines might be used in experiments outside contained facilities. He referred to a recently completed field test at Clemson University supported in part by the Monsanto Company. He introduced Dr. Ellis Kline and Dr. Dan Kluepfel to describe the results of the Clemson/Monsanto field test to the Committee.

Dr. Kline presented the scientific background of the Clemson/Monsanto field test. The experiment involved the common soil bacterium Pseudomonas fluorescens which was genetically modified with lac ZY marker genes from E. coli. The lac ZY genes enabled the modified Pseudomonas to utilize the sugar lactose as a nutrient in contrast to naturally occurring Pseudomonads which cannot utilize this nutrient. This added nutritional capability combined with fluorescence and a dye-mediated color reaction provided investigators with a specific technique for identifying and tracking the modified microorganism in the soil.

The Clemson researchers, according to Dr. Kline, tested the organisms thoroughly in the laboratory before introducing them into the field environment. In the laboratory, there was no genetic exchange from modified to unmodified organisms over ten generations.

Dr. Kline outlined the public relations aspect of the test. He said that both Clemson and Monsanto were sensitive to possible public concerns about the field test and they conducted over 100 meetings to inform the public about the purpose and safety provisions of the test.

Dr. Kline described two major objectives of the field test. They were to study 1) the performance of the modified organism in the field particularly with regard to root colonization, longevity on crops, and timing with respect to disease and pests and 2) environmental effects of the organism including movement of the microorganism in the soil, survival to successive crops, and the transfer of genes to other organisms.

Dr. Kline then introduced Dr. Dan Kluepfel to brief the Committee on some of the microbial/ecological results of the test.

Dr. Kluepfel posed the question of how well the behavior of an organism released into the environment can be predicted from contained laboratory experiments. He presented information on the growth and die-off of microorganisms in the field and in growth chambers. He called attention to the similarity of the growth curves and interpreted this along with other information as an indication of the possible predictive value of growth chamber studies for the behavior of outdoor soil-borne rhizosphere-inhabiting microorganisms. He then presented some preliminary data on the spread of root colonizing bacteria by mechanisms such as water droplets and insect vectors to other parts of the plant such as epiphytic surfaces and the vascular tissues of stems and leaves.

Dr. Osburn thanked Dr. Kline and Dr. Kluepfel for sharing their preliminary research results with the Committee.

SCOPE OF ORGANISMS COVERED BY GUIDELINES

Dr. Osburn turned the attention of the Committee to the scope of organisms covered by the guidelines. He reminded the Committee that the role of ABRAC on the scope issue is advisory. The final decision on the definition of scope will rest with the leadership of USDA and the Biotechnology Science Coordinating Committee (BSCC).

Ms. Cordle referred the Committee to draft Document No. 125 distributed prior to the meeting. This document represented the work of the BSCC Subcommittee on Scope with review by the EPA and BSCC. She emphasized that the draft is not intended to be a verbatim rule for all agencies, but it is intended to be guidance. She mentioned that the draft was under review by the Administration's Council on Competitiveness. She indicated the draft had not been unanimously accepted by the BSCC Subcommittee, but it did represent the sense of the majority of the group.

Ms. Cordle noted that the current version of the USDA guidelines (Document No. 124) contained a definition of scope somewhat different from that of the BSCC. She said this reflected the views of the ABRAC Guidelines Working Group which collectively thought its definition was clearer. Ms. Cordle called the attention of the Committee to the exemptions from the definition of scope which, in her view, were the most important part. She said the first three exemptions in the guidelines definition of scope were fairly clear and depended on whether an organism was a plant, animal, or microorganism. She acknowledged that criteria for the fourth and fifth exemptions were somewhat less clear and might benefit from further discussion.

Dr. Tolin explained how the Guidelines Working Group developed its recommendations for exemptions from the definition of scope of organisms. She said the details were contained in the transcript and minutes of the Guidelines Working Group meeting of February 27-28, 1990.

Dr. Bulla asked about the source of the exemption concerning the movement of nucleic acids using physiological processes in Document No. 125, page 4, section 3(b). Ms. Cordle responded that it was a verbatim statement from the BSCC, and that the subcommittee could not develop any different language.

Ms. Cordle summarized the proposed exemptions from the BSCC general scope definition for the Committee.

Dr. Andow said that exclusion of some techniques based on process seems contrary to the basic principles of the guidelines.

Dr. Whitmore stated that a major consideration is familiarity with the procedures. He questioned whether product can be the only basis for separation; process has to be considered as well. Familiarity was part of the logic in his view.

Dr. Sorensen suggested adding language to clarify the exclusion where familiarity with techniques, not outcomes, is the basis. Dr. Andow concurred, if the basis of the familiarity can be described and supported.

Dr. Payne expressed the view that it is a mistake to draw conclusions of exclusion on the basis of techniques. He felt that the familiarity criterion is shorthand for confidence in ranges of risks, knowledge of phenotypes, and with the products resulting from the techniques. Dr. Payne said that exclusions do not need additional oversight where the processes and products are familiar.

Dr. Tolin asked if the list of techniques deleted from the previous document had been approved by the BSCC subcommittee. Ms. Cordle explained the reasons for dropping the examples.

She said the BSCC subcommittee felt that inclusion of examples might cloud the decisions.

Dr. Tolin said that this was a major change that needs approval of ABRAC. The material that was deleted reflected two years of discussion and agreement. Dr. Vidaver recalled that she and other ABRAC members are repeatedly asked which techniques are covered and which are deleted and that mentioning them specifically helps to communicate with the intended audience.

Dr. Osburn tried to get closure on the discussion. He asked if there was any consensus that ABRAC could reach.

Dr. Tolin moved to transfer text from Document 119, page 6, lines 18-25 to immediately after the first sentence of section III-B, of the April 12, 1990 draft of the Guidelines (Document 124). Dr. Tolin contended that the deleted material clarified for investigators what will be included in the Guidelines.

After discussion among the committee, several members asked to be provided copies of the text to be transferred from Document 119, so they could evaluate the deleted language before approving its inclusion.

This suggested action was accepted by Dr. Osburn who tabled Dr. Tolin's motion until the members could review the language from Document 119.

DR. CHARLES E. HESS

Dr. Osburn introduced Dr. Charles E. Hess, Assistant Secretary for Science and Education.

Dr. Hess updated the Committee on the progress of the BSCC Scope Subcommittee. He indicated that the BSCC had discussed an interagency definition of the scope of organisms to be covered by guidelines and regulations and forwarded it for administrative review. He said the group understood that its proposed definition of scope was not perfect, but no one had been able to suggest an alternative that was acceptable to a majority of the members. Dr. Hess indicated that Dr. Allen Bromley, the President's Science Advisor, felt that the scope definition was a significant policy issue and needed review at a higher level.

Dr. Hess also noted that the Vice President's Competitiveness Council was interested in the scope definition and had requested that it be presented to the Council. A subcommittee of the Competitiveness Council had already included the scope definition on its agenda.

Dr. Whitmore asked what the Competitiveness Council is. Dr. Hess replied that it is a council established by the Executive Branch to examine issues which may influence U.S. economic competitiveness. Its formation was triggered by concern that

the U.S. may not be as proficient at translating basic research into successful products as some other nations are. Its focus as far as biotechnology is concerned is the development of appropriate oversight to protect human health and the environment without imposing a counterproductive regulatory burden on the industry.

SCOPE OF ORGANISMS COVERED BY GUIDELINES (continued)

Dr. Osburn invited Ms. Cordle to resume the discussion of scope of organisms. Ms. Cordle summarized for the Committee the exemptions from the general scope definition for plants, animals, microorganisms, non-coding non-expressed nucleotide sequences, and a fifth exemption involving familiarity as a criterion of safety with respect to environmental effects.

Dr. Korwek asked whether insects would fit under the exemption for animals or under microorganisms as defined by the criterion of invisibility to the unaided eye. Dr. Vidaver replied that insects would not normally be considered to be microorganisms.

Dr. Vidaver then explained how the definition of microorganism was developed in the Guidelines Working Group. She stated that the proposed definition in the draft guidelines (Document 124 at II-A-4-b) resulted not from scientific considerations, but from an evidently widespread concern and fear on the part of the public about living organisms that cannot be seen with the unaided eye. Dr. Vidaver emphasized that the working group did not necessarily consider conventionally modified organisms to be safe, but it was not aware of any new information bearing on the question.

Dr. Korwek questioned whether the basis for the exemption for microorganisms had been sufficiently articulated. He expressed particular concern about the suggestion that a familiarity standard is being used without sufficient consideration of the intended use and the environment. He observed that the familiarity standard under discussion was not consistent with that in the National Research Council report on release into the environment.

Ms. Cordle acknowledged that familiarity is being used in a different sense for microorganisms than it is for plants and animals. She asked if anyone is of the view that we should not go forward with the exemption for microorganisms as it stands.

Dr. Letourneau suggested that the level of familiarity with microorganisms may be so low that it needs a different standard than that for plants and animals. She supported Dr. Andow's earlier suggestion of a three-part concept of familiarity consisting of the organism, the trait being modified, and the environment into which it is placed.

Dr. Wodzinski, American Society for Microbiology, expressed support for Dr. Andow's three-part concept of familiarity adding that genetic stability is also important.

Dr. Andow questioned the scientific basis of natural occurrence of an organism as a standard of familiarity. Dr. Letourneau said that even though the language on pp. 15-17 of Document 125 did not explicitly say that natural occurrence is equivalent to safety, it is too easy to be read that way. She said she preferred the alternative exemption on page 17, which provides another oversight mechanism for microorganisms and uses research results to gain familiarity.

Dr. Vidaver responded with the argument that the microorganism definition needs to be able to extend to commercial agriculture. The alternative on page 17 of Document 125 would appear to hinder this.

Dr. Fraley asked if there was a basic confusion between familiarity and acceptable risk. He sensed that some members were arguing for acceptable risk, instead of allowing familiarity with the organism to establish the exclusion.

Dr. Osburn asked if the Committee could come to closure on this issue and incorporate language on environment and trait, as suggested by Drs. Andow and LeTourneau, and get acceptance by the committee.

Dr. Tolin said she did not believe that it is possible to agree totally on the exclusion principles. In her view, the ones presented didn't claim to be based upon scientific arguments. She suggested the definitions be modified to make it clear that these are operational definitions for the purposes of adopting Guidelines.

Dr. Bulla suggested that for the benefit of the scientific community, more than the public, it would be useful to spell out the exclusions of microorganisms more clearly. He suggested a modification of the definition of microorganisms such as the following: "For purposes of these Guidelines, microorganisms are defined as any organism, macromolecule, or entity capable of reproducing. These include viruses, viroids, bacteria, protozoa, fungi, some algae, and nematodes." In Dr. Bulla's view, this was an operational definition that encompassed all reproducing entities with which the scientific community and public have biosafety concerns.

Dr. Osburn accepted the suggestion, in principle, and asked Drs. Bulla, Vidaver, Tolin and Wodzinski, to write out an exact definition for later consideration. The definition developed by this group is included as Appendix 1.

Ms. Cordle moved on to exclusion 4, beginning on page 17 of Document 125 and asked if there were any concerns. After

discussion the committee decided to modify the subgroup's submission and to adopt the following for section III-B-4 of the draft Guidelines: "Organisms which have been modified by the introduction of non-coding, non-regulatory, non-expressed nucleotide sequences that cause no phenotypic or physiological changes in comparison to the parental organism and where the IBC has been notified."

Dr. Osburn had the changes read back, and asked if there was consensus. With no objections or further discussion, he stated that a consensus had been reached and asked Ms. Cordle to proceed.

Ms. Cordle moved on to exclusion 5 and asked if a list of excluded organisms could be developed? If so, it provides an opportunity to look at the product in the context of familiarity and risk.

Dr. Korwek expressed reservation about exclusion 5 concerning demonstration of familiarity to USDA. He contrasted exemption from the guidelines with exemption from oversight. He said an exemption from oversight whereby an applicant has to seek regulatory clearance for the exemption is not an exemption from oversight. He recommended that exclusion 5 be placed somewhere else in the text.

Dr. Collis, representing the University of Florida Institutional Biosafety Committee (IBC), commented on exclusions 4 and 5. He said that most researchers are not moving forward with field research of this kind at present because the appropriate guidance is not yet in place. He said he hoped the guidelines would be an instrument to help institutions help researchers do the experiments they would like to do in a safe manner. If the exclusions require researchers to prepare applications to USDA, the resulting workload could be enormous and research progress would be impeded. He recommended that local IBC's, supplemented with the appropriate expertise, could handle most proposals for research of this type and save USDA the time and resources.

Dr. Tolin expressed the view that it is important to keep exclusion 5 where it is, although she suggested it might be supplemented by a list of excluded organisms developed by ABRAC.

Dr. Fraley expressed support for exclusion 5 and for local IBC review of proposals with USDA notification.

REPORT OF GUIDELINES WORKING GROUP

Dr. Osburn asked Dr. Tolin to report on the discussions of the Guidelines Working Group.

Dr. Tolin summarized for the Committee the deliberations and actions of the Guidelines Working Group on definitions, scope of organisms, and the organization and content of the draft

guidelines. She also referred to a recently released report of the Organization for Economic Cooperation and Development (OECD) entitled "Good Developmental Practices: Small Scale Field Research with Genetically Modified Plants and Microorganisms - A Discussion Document" and observed that its approach is generally consistent with that of the draft guidelines.

Dr. Osburn thanked Dr. Tolin for her report on the meeting of the Guidelines Working Group.

DEFINITION OF CONTAINED FACILITY

Dr. Osburn asked Ms. Cordle to review for the Committee the issue of the definition of contained facility.

Ms. Cordle referred to the definition of contained facility in the current draft of the guidelines, Document 124, as an enclosed structure with walls, roof, and floor. She indicated that OAB staff had met with NIH/RAC staff on this issue and that a mechanism was in place to achieve a smooth transition from contained research covered exclusively by the NIH Guidelines to agricultural research covered by the USDA guidelines. She indicated that the draft USDA guidelines can accommodate research in greenhouses that may not meet all the requirements of the NIH for contained greenhouse research.

Dr. Korwek asked how the Auburn transgenic fish proposal reviewed earlier by the Committee would be handled under the revised definition of contained facility. [OAB staff note: The NIH/RAC had determined that the adult transgenic fish in the Auburn experiment were segregated by sex and were therefore biologically contained under the NIH Guidelines.] Ms. Cordle replied that as long as the research is moving outdoors, it would be covered by the USDA guidelines.

Dr. Witter asked whether an animal barn would be considered contained. He expressed doubt that it would be constitute containment for microorganisms.

Dr. Tolin replied that a barn would normally constitute confinement for an animal. However, she recalled that proposed Appendix Q of the NIH Guidelines required Biosafety Level 2 or higher for animal-associated microorganisms. Her interpretation was that this would not include an open barn or an open pen. She further concluded that research on animals without infectious microorganisms or with viruses that are only vertically transmitted would be appropriate research for a barn or pen setting.

SCIENTIFIC REVIEW OF CLASSIFICATION OF ORGANISMS

Dr. Osburn asked Dr. Phillips to address the scientific review of the classification of organisms described in the draft

guidelines. Dr. Phillips indicated that Dr. Tolin had covered much of what he had to say in her report on the Guidelines Working Group. He used an overhead projector to display a flowchart that he and Dr. Gerber had developed showing different pathways for the scientific review of proposals. Several Committee members suggested changes to clarify the flowchart.

Dr. Korwek stressed the need for the flowchart to be accurate, complete, and concise if it is to be included in the guidelines. He alerted the Committee to the possibility problem situations caused by someone relying on the flowchart without reading the detailed text. He recommended that the flowchart include a notice that reading the text is necessary to achieve an adequate understanding of the proposal review process.

Dr. Sorensen raised the question of how many examples of the classification of organisms should be included in the guidelines. Dr. Collis, speaking for IBC's, encouraged the inclusion of as many examples as possible without making the document unwieldy.

Dr. Osburn directed the Committee's attention to Section VI of the guidelines on determination of the level of safety concern for parental organisms.

Dr. Korwek commented that the definition of safety as "conditions with virtually no potential for adverse effects on human health, or managed or natural ecosystems" may be so stringent that it cannot be met. He referred to the NIH standard which is "absence of significant risk."

Dr. Tolin agreed and suggested deletion of the words "virtually no" from the USDA guidelines' definition of "safe."

Dr. Vidaver suggested insertion of the phrase "minimum potential for unwanted adverse effects on human health or on managed or natural ecosystems."

Dr. Gerber contrasted field research with release for commercial purposes and suggested that the objectives with respect to spread of the organism could be different.

Dr. Tolin contended that a researcher can conduct a safe experiment in which the organism is allowed to spread if there are no consequences.

Dr. Osburn suggested defining safety as "conditions determined with reasonable certainty to have negligible risk."

Dr. Tolin suggested the use of the phrase "negligible or acceptable risk."

Dr. Osburn suggested the following definition for the Committee's consideration: "Safety" or "safe" refers to a

"condition determined with reasonable certainty to have negligible or acceptable risk to human health or managed or natural ecosystems."

Dr. Korwek pointed out that "negligible" is different from "acceptable" and that the definition as read therefore contains two standards for safety.

Dr. Vidaver suggested that the Committee consider a zero level of safety concern for certain modified organisms. As examples of organisms not posing special safety concerns when produced by Type 1 and Type 2 genetic modifications, she mentioned yellow petunias, striped cows, and yogurt microorganisms that produce a strawberry flavor.

Dr. Korwek asked if Dr. Vidaver's proposed Level 0 was essentially Level 1 without IBC review and Dr. Vidaver replied that effectively it was.

Dr. Young suggested that Dr. Vidaver draft some language about her proposal so the ABRAC could better evaluate it. Dr. Osburn and Dr. Vidaver agreed.

CONFINEMENT AND OVERSIGHT

Dr. Osburn asked Dr. Gerber to update the Committee on the confinement and oversight sections of the draft guidelines.

Dr. Gerber recalled that the Guidelines Working Group, at its February, 1990 meeting, had asked the OAB staff to develop information on confinement and oversight. Dr. Gerber said his approach started from three assumptions, 1) that the level of safety concern can be objectively established, 2) that the level of safety concern determines the level of confinement, and 3) that the IBC/OAB/ABRAC system is responsible for confinement assurances. He acknowledged that these assumptions may be debatable.

Dr. Gerber then walked the Committee through the flowchart shown previously by Dr. Phillips with special emphasis on confinement implications [Appendix 2]. Dr. Gerber presented specific confinement measures for organisms grouped into the following classes: terrestrial plants, terrestrial animals, aquatic plants, aquatic animals, microorganisms, and insects [Appendix 3].

Dr. Gerber asked Dr. Collis to comment on the proposed confinement measures from the perspective of a university-based IBC.

Dr. Collis expressed the view that the confinement information presented was more workable than previous versions. However, he did question the security requirements as being somewhat excessive.

Dr. Young asked Dr. MacKenzie to describe what the National Biological Impact Assessment Program (NBIAP) is doing in terms of specific organisms and specific experiments.

Dr. MacKenzie indicated that the information presented by Dr. Gerber was generally consistent with what NBIAP is doing. He said that NBIAP has classified organisms used in agricultural research into 79 categories so that confinement measures for them could be handled specifically in accordance with the characteristics of the organisms.

Dr. Andow asked Dr. MacKenzie if the Committee could obtain a listing of the 79 groups of organisms. Dr. MacKenzie replied that he did not have the list with him, but it could be provided.

Dr. Osburn asked the Committee to address the question of what information should be included the in main text of the guidelines and what should be in appendices.

Dr. Tolin moved that the Committee accept the concept of the confinement revisions developed by OAB staff and arranged by organism group and that the material be included in an appendix rather than in the body of the guidelines. After some discussion, the Committee voted unanimously (9 in favor, 0 opposed, 0 abstentions) to approve the motion.

Dr. Osburn recessed the meeting until 9:00 a.m. the next morning.

April 24, 1990

Dr. Osburn reconvened the meeting. He said that time had been provided to Dr. Jane Rissler of the National Wildlife Federation to make a statement for the record.

Dr. Rissler read a statement presented in behalf of the Biotechnology Working Group composed of representatives of public interest organizations, a state agricultural agency, and citizen activists. Dr. Rissler stated its purpose as strengthening the influence of the public interest community on the development of biotechnology. She said the group had recently issued a report entitled Biotechnology's Bitter Harvest.

Dr. Rissler conveyed the serious concern of the group at the lack of representation on the ABRAC of members of the public interest, environmental, consumer, and family farm communities. She expressed particular dismay regarding the recent rejection by the Secretary of Agriculture of an ABRAC nominee from the public interest community. She speculated that the rejection occurred because of the nominee's recent criticism of some of USDA biotechnology policies. She said the membership of the

ABRAC ought to reflect the diversity of the affected communities including researchers, producers, users, and the public.

Dr. Osburn thanked Dr. Rissler for her comments.

SUBMISSIONS UNDER THE GUIDELINES

Dr. Osburn invited Dr. David MacKenzie to describe how the NBIAP could help researchers to prepare submissions under the guidelines.

Dr. MacKenzie described the principal components of NBIAP as information exchange, biological monitoring, biosafety research, and genome mapping. Under the information exchange component he described the NBIAP electronic bulletin board which currently provides over 900 subscribers with access to 13 databases on agricultural biotechnology. He also described several databases currently under development.

A second part of the program was biological monitoring. Dr. MacKenzie described an ongoing survey of scientists who have conducted field tests concerning their design, protocols, procedures, techniques, monitoring, and results including negative results which are frequently not published. He expressed the view that such data and information may provide a basis for determining if it is appropriate to relax regulatory requirements for certain kinds of organisms and experiments.

The third component of the NBIAP is biosafety research. Dr. MacKenzie contrasted the expression of support for the program by a number of organizations with the current absence of significant funding. He expressed hope for the distribution of significant funding for the program in the future through a competitive, peer-reviewed grants program.

A fourth component of the NBIAP is genome mapping. Dr. MacKenzie described several levels of activity in a plant genome mapping program that he co-chairs with a colleague from the Agricultural Research Service. These included low-resolution maps for a large number of crops, high-resolution maps for a few selected crops, a complete physical map for one species, and coordination of methodology and analysis with the human genome project.

Dr. Tolin expressed concern about the different formats for submissions under the guidelines relative to the generalized outline of submissions for Federal permits. Dr. MacKenzie expressed willingness to reprogram the NBIAP formats as needed. Dr. Young expressed the view that while the formats are not identical, they track fairly well. Dr. Payne stressed that the focus should be on information relevant to the decision-making process rather than on format.

Dr. Osburn thanked Dr. MacKenzie for his report.

RESEARCH GUIDELINES

Dr. Osburn outlined his goals for the remainder of the meeting. These were 1) ABRAC approval or acceptance of the draft guidelines, 2) the development of instructions to OAB to prepare an executive summary of the guidelines, and 3) ABRAC approval to proceed with publication of the notice of intent to prepare an EIS.

Dr. Osburn asked Dr. Tolin to lead the Committee in a section-by-section discussion of the guidelines.

Dr. Tolin proceeded with a detailed review of the guidelines. She said she had no specific changes in the "Purpose" section at this time, but she was receptive to suggestions. Members discussed possible changes in the "Purpose" section. Dr. Osburn observed that most of the changes appeared to be wordsmithing in nature and they could be submitted to OAB for consideration. He urged Committee members to focus on conceptual issues.

Dr. Young, in response to questions from members, outlined the process of Department and agency review that he envisioned for the guidelines. He asked Mr. Robinson to depart from the agenda and give his presentation on the EIS process at this time.

Mr. Robinson outlined the major features of the National Environmental Policy Act (NEPA) including environmental impact statements (EIS) for the Committee. He pointed out that the statute, regulations, and case law all require public participation in the EIS process and he urged the Committee to moderate its concern for a scientifically perfect and error-free document at this time. He then discussed proposed actions, scoping, affected environment, alternatives, mitigation procedures, and cooperating agencies under the NEPA.

Dr. MacKenzie asked how long the EIS process would take.

Mr. Robinson replied that a recent EIS he was involved in took 14 months from notice of intent to draft EIS and 24 months to a final EIS.

Dr. Vidaver asked who decided that the guidelines are likely to have a significant environmental effect.

Mr. Robinson replied that he didn't know who made the decision, but that the context and intensity of the action are frequently considered in making such decisions.

Dr. Tolin asked if there were precedents for categorical exclusion of research.

Mr. Robinson replied that he could not answer the question, but that the CEQ regulations state that technology will be subject to NEPA.

Dr. Tolin continued the discussion of the guidelines. Members discussed various interpretations of the definitions in the guidelines particularly with regard to groups such as insects, nematodes, fungi, mycoplasmas, and prokaryotic and eukaryotic algae.

Dr. Tolin read a suggestion from Dr. Sorensen to add the following language to the section on applicability and scope: "familiar enough with the following techniques to confidently predict the outcome of the genetic modification, the guidelines do not apply to..."

Dr. Andow offered an expanded version of Dr. Sorensen's suggestion expressed in terms of familiarity and existing oversight by regulatory agencies.

Dr. Tolin expressed the view that the intent of Dr. Andow's suggestion was covered elsewhere in the guidelines and it was not necessary to insert it here.

Ms. Cordle contrasted the use of explanatory text in the guidelines with that of a legal standard or statement of applicability. She noted that the latter would be more susceptible to legal challenge. Dr. Korwek supported Ms. Cordle's view.

Dr. Tolin referred to the motion she had made the previous day which had been tabled. She offered an amendment so that her motion would read, "The guidelines are intended to apply to genetically modified organisms resulting from the use of new methods such as [list of methods] because there is not the familiarity with such organisms to predict confidently the outcome of the modification and the organisms' activity upon introduction into a natural test site." Dr. Vidaver expressed support for the amendment.

Dr. Korwek argued that the use of the word "familiarity" in the amendment was subject to vagaries of interpretation which could lead to legal challenges.

Dr. Payne argued against adoption of the amendment.

Dr. Vidaver asked how researchers are going to know how to apply the guidelines if some kind of explanation or list of techniques is not included.

Dr. Tolin observed that the simplest way to proceed at present would be to leave the applicability/scope language as it is now without a list of techniques and without an explanation of where it applies and where it doesn't apply.

Dr. Korwek expressed doubt that the Committee could resolve the applicability/scope question at the present time. He said it

may be addressed in the preamble to the guidelines or in the practice of various NEPA proceedings, but it would take considerably more time to resolve than the Committee had at present.

Dr. Tolin, in order to move the discussion along, withdrew her motion that a list of techniques be added to the applicability/scope section.

SCOPE DEFINITION EXEMPTIONS 1-4

Dr. Tolin directed the Committee's attention to exemptions 1, 2, and 3 from the scope definition. Committee members did not achieve total agreement on the wording of these exemptions for plants, animals, and microorganisms, but they consented to go forward with them in order to initiate the process.

Dr. Tolin directed the Committee's attention to exemption 4 for non-coding, non-expressed nucleotide sequences. She recommended that the reference to the IBC be transferred to a different section of the guidelines and that the term "non-regulatory" be added to exemption 4.

SCOPE DEFINITION EXEMPTION 5 (GUIDELINES SECTION III-B-5)

Dr. Tolin directed the Committee's attention to exemption 5 on organisms for which it can be demonstrated to USDA that there is sufficient familiarity with the organism to assess its environmental effects. She expressed the view that it is important that the guidelines retain exemption 5.

Dr. Witter referred to someone's suggestion that decisions on exceptions be delegated to IBC's and he questioned if the Committee had reached a consensus on that. Ms. Cordle expressed doubt that an IBC could grant a national exclusion.

Dr. Payne distinguished between exclusions for specific organisms and categories of organisms with which there is indicative experience. He recommended retention of exemption 5 for the flexibility to exclude categories up front.

Dr. Whitmore cited Lac-Z-containing organisms as examples that are not producible under exemptions 1-4, but are nevertheless safe in the view of many. He recommended a return to the simple language suggested by Dr. Tolin which she reiterated as "other specific exemptions as approved by USDA." [OAB staff note: This is referred to hereinafter as "the simple language."]

Dr. Korwek supported the return to the simple language.

Dr. Vidaver moved to substitute the simple language in Section III-B-5.

Dr. Payne said the intent of exemption 5 was to encompass organisms not mentioned in the previous exemptions, but with which there is familiarity. He said that adoption of the simple language could undercut the effort of the BSCC Scope Subcommittee. He recommended that the Committee table the motion and consult with Dr. Hess, the Chair of the BSCC Scope Subcommittee.

Dr. Fraley suggested retaining the present language and adding the simple language at the end of Section III-B-5.

Dr. Korwek expressed strong concern about Section III-B-5 in its present form and expressed opposition to any option other than the simple language.

Ms. Cordle recalled that a number of agencies and professional societies viewed Exemption 5 as very important and the familiarity language as absolutely critical.

Dr. Korwek argued that the familiarity standard is not always met in exemptions 1-4.

Dr. Tolin replied that the familiarity standard is not imposed in exemptions 1-4.

Dr. Osburn proposed a straw vote to get a sense of the Committee on Section III-B-5. He requested a show of hands from those in favor of Section III-B-5 as it now stands with demonstration to USDA as the only change.

Dr. Tolin requested enumeration of three alternatives prior to the vote.

Dr. Korwek requested an opposed vote prior to further discussion.

Dr. Osburn requested a show of hands from those opposed to retention of Section III-B-5 as is [Document 124, pp. 6-7]. The result was 6 opposed, 3 not opposed.

Drs. Young and Osburn concluded that the sense of the Committee is that the language needs to be changed.

Dr. Vidaver enumerated two remaining alternatives, to add the simple language or to substitute the simple language.

Dr. Osburn requested discussion first on adding the simple language at the end of Section III-B-5.

Dr. Korwek asked if the added language would follow the language the Committee just negated. Dr. Osburn replied "yes."

Dr. Osburn requested a show of hands of those in favor of adding the simple language to Section III-B-5. The result was 0 in favor, 7 opposed.

Dr. Osburn requested discussion on substituting the simple language for Section III-B-5.

Dr. Tolin restated the motion under consideration as substitution of Section III-B-5 by the language "other specific exclusions as approved by USDA."

Several members discussed adding a short sentence.

Dr. Young said "Other specific exclusions as approved by USDA."

Dr. Osburn said "All those in favor of that, please signify by raising your right hand." The result was 8 in favor, 0 opposed, 1 abstention.

Dr. Osburn concluded that the last vote reflected the sense of the Committee that Section III-B-5 should read in its entirety: "Other specific exclusions as approved by USDA."

Mr. Robinson reminded the Committee that a NEPA analysis still needs to be applied to exclusions as approved by USDA.

Dr. Payne expressed the view that the amended Section III-B-5 creates a significant amount of work for the staff.

Dr. Korwek expressed the view that the amendment changed nothing and that a NEPA assessment would have been required with the previous language whether a standard for exemption was included or not.

OTHER SECTIONS OF THE GUIDELINES

Dr. Tolin then moved on to other sections of the draft. In section VI-D, (Document 124, p. 16, lines 6-7), she asked that the Working Group's original language be restored, namely, "Note that the level of safety concern is not derived from the sum or the mean of the individual levels assigned to the specific attributes described in Action II (Section VI-B). Neither is it controlled by the highest or lowest levels assigned to the individual attributes. The level of safety concern is based on the potential for adverse effects on human health or on managed or natural ecosystems."

The language on line 12-14, page 16, Document 124: "The assignment of the level of safety concern requires scientific judgement, which should be justified in the submission document." was modified to read: "Principal investigators must exercise sound scientific judgement in evaluating the relative

importance of the attributes in Action III (Section VI-C) in order to assign the level of safety concern. These actions should be justified in the submission document."

Committee members expressed concern that this makes the IBC task more difficult. In their view, the IBC can conduct this determination, but they need clear guidelines on how to apply the level of safety concern criteria.

Dr. Tolin invited Dr. Vidaver to discuss her proposal for a level of safety concern 0. Dr. Vidaver responded that she questioned how the Guidelines could recognize that there are some organisms that have adverse effects, but are still beneficial. She referred to page 12, lines 19-25, Document 124, where there is no mention of possible benefits of the organisms. There were no suggested or accepted changes in response to her concern.

Dr. Tolin suggested wording changes for page 10, line 25, Document 124. She suggested that the word "studied" be replaced with "identified and evaluated". She also emphasized that the examples of Appendix 1 need to be realistic, not hypothetical. In response, the word "hypothetical" was deleted from line 24, page 11, Document 124.

Dr. Tolin moved on to Section VII. Members discussed text on p. 19 about the procedures for modifying an initial level of safety concern determination. Members asked for an additional sentence that expresses the thought that a type of modification can be reclassified to a different level of safety after consideration of the information obtained from field tests.

On page 20, line 21 and page 21, line 7, Dr. Tolin suggested the addition of the word "unwanted" immediately prior to "adverse effects". After discussion, this suggestion was not accepted by the Committee.

In Section IX, page 25. The Committee agreed to delete the sentence on line 8-13 and replace it with original language of the Working Group. The sentence should read: "The primary goal of confinement is to limit the potential of organisms to affect human health or managed or natural ecosystems adversely."

On page 27, Section IX, The Committee accepted, in concept, the levels of confinement. There was a sense that the confinement levels need to be reordered and reworked. It was agreed that they will be applied to classes of organisms. The detailed discussion of confinement measures by organism classes should be taken from text of the guidelines and added to the Appendix.

The Committee asked the OAB staff to put detailed lists of specific confinement measures by organisms classes into the Appendix. The Committee expressed a preference for the text to be broader and to direct principal investigators to use the

Appendix material in their development of proposals using the intent of the Guidelines. All members agreed that more detail is needed and the lists were a good start.

Dr. Osburn assigned a timeframe of 2 weeks for revision of section IX and other changes to the guidelines.

Dr. Tolin reviewed Section X, Submissions under the Guidelines. She discussed the purpose and application of the Section. On page 43 she suggested that "documentation" be added as a requirement for the data submission. Otherwise, section X-A was accepted by consensus as written.

The Committee reviewed Section X-B and did not make any changes in it.

Dr. Tolin asked for review of Section XI, Oversight of Research Safety Protocols. It was apparent that this Section was not parallel to Section V. The consensus was that Section V needed to be revised to include a requirement for IBC approval. Mr. Stern and Dr. Korwek agreed to work on this.

The Committee deleted the words "...taking into account the possible consequences of an improper determination of the level of safety concern" from page 46, lines 3-6.

The Committee noted an inconsistency in the standard for an exception. Members indicated that this should be the same as in section III-B-4.

The Committee agreed that a new section XI-D is needed to cover research that requires USDA approval. This refers to the exemptions, and will replace XI-C-5. The remainder of IX-C-5, lines 18-23, page 47 was deleted.

The Committee discussed the process for submissions though the IBC and directly to USDA. The intent was that a principal investigator could directly submit proposals to USDA when the IBC has turned down the proposal. This would be for getting another level of decision, similiar to an appeal. The Committee did not believe that this should be allowed. Dr. Collis pointed out that all submissions still have to go through the IBC. Therefore, there is no need for all the discussion in the guidelines at page 46, line 18-23. The committee agreed to its deletion.

There was a discussion and review of page 16. Dr. Vidaver explained proposals for change on pages 16, 25, and 48, all of which related to her proposal for a new level of safety concern 0. Dr. Collis suggested making IBC notification rather than approval the basis for a new category.

Dr. Osburn said that his sense was this is an alternative to the direction as written. The conclusion of the discussion was to

revise the guidelines to create a level 0, or redrafted category 1. This would be based on IBC notification and approval. The Committee asked the OAB staff to redraft this section and report back in the same timeframe as the other changes.

Dr. Tolin asked if there were any changes for Section XII. Dr. Collis questioned the meaning of "prompt" on page 49, line 16. He suggested that the guidelines be more specific on this notification.

Dr. Osburn said it appeared that all major concerns had been considered. He encouraged acceptance of the guidelines as a proposed action for the notice of intent. He suggested that OAB initiate the process by forwarding the draft guidelines for review and comment by appropriate agencies, and to begin the EIS process. He acknowledged the concerns that some members have with the guidelines as drafted, and said that his proposed action does not constitute or imply approval of the guidelines. It does mean that the draft guidelines are acceptable as a proposed action for initiating the EIS process.

The Committee, without expressing agreement with the document, accepted Dr. Osburn's proposal, and asked that the OAB forward a working draft, revised in accordance with the sense expressed in this meeting, for review and comment by appropriate agencies, and to initiate the EIS process under NEPA. The Committee asked that a draft of a letter to other agencies requesting participation as cooperating agencies also be prepared.

Dr. Osburn asked the ARS representative to comment briefly on the brucellosis vaccine proposal. The ARS representative explained that the initial application had come to ABRAC from Texas A&M University. The research will be conducted within contained facilities, and is expected to lead to field trials under the veterinary biological regulations of APHIS.

Ms. Cordle provided a brief update on the status of the proposal involving transgenic fish at Auburn University. She said there have been comments on the EA. Staff members have met with commentors to better understand their concerns. OAB has assembled a team to examine the issues of possible escape, population genetics, and survival of escaped fish in the environment. The Experiment Station Director had sent a letter proposing a new, more secure pond site, thereby improving the prospect for biosafety.

Dr. Young announced the upcoming OAB/APHIS Conference on the results of field tests. The conference will be in South Carolina in November and he invited ABRAC members to attend.

Dr. Young said the next ABRAC meeting is scheduled for June 21-22, 1990.

Dr. Osburn expressed thanks to all members for their attendance and participation. He thanked the subcommittees for their work in getting the documents ready to review at this meeting. He added appreciation for the work of the OAB staff. He thanked invited guests and observers and adjourned the meeting at 3:01 p.m.

W. Milton Robinson

W. Milton Robinson
Rapporteur

Alvin L. Young

Alvin L. Young
Executive Secretary

Daniel D. Jones

Daniel D. Jones
Rapporteur

Bennie I. Osburn

Bennie I. Osburn
Chair

APPENDICES

1. Definition of "Microorganism" Developed by ad hoc Subgroup
2. Flowchart and Associated Confinement Measures
3. Working Document 1 - Confinement [Measures for Six Categories of Organisms]

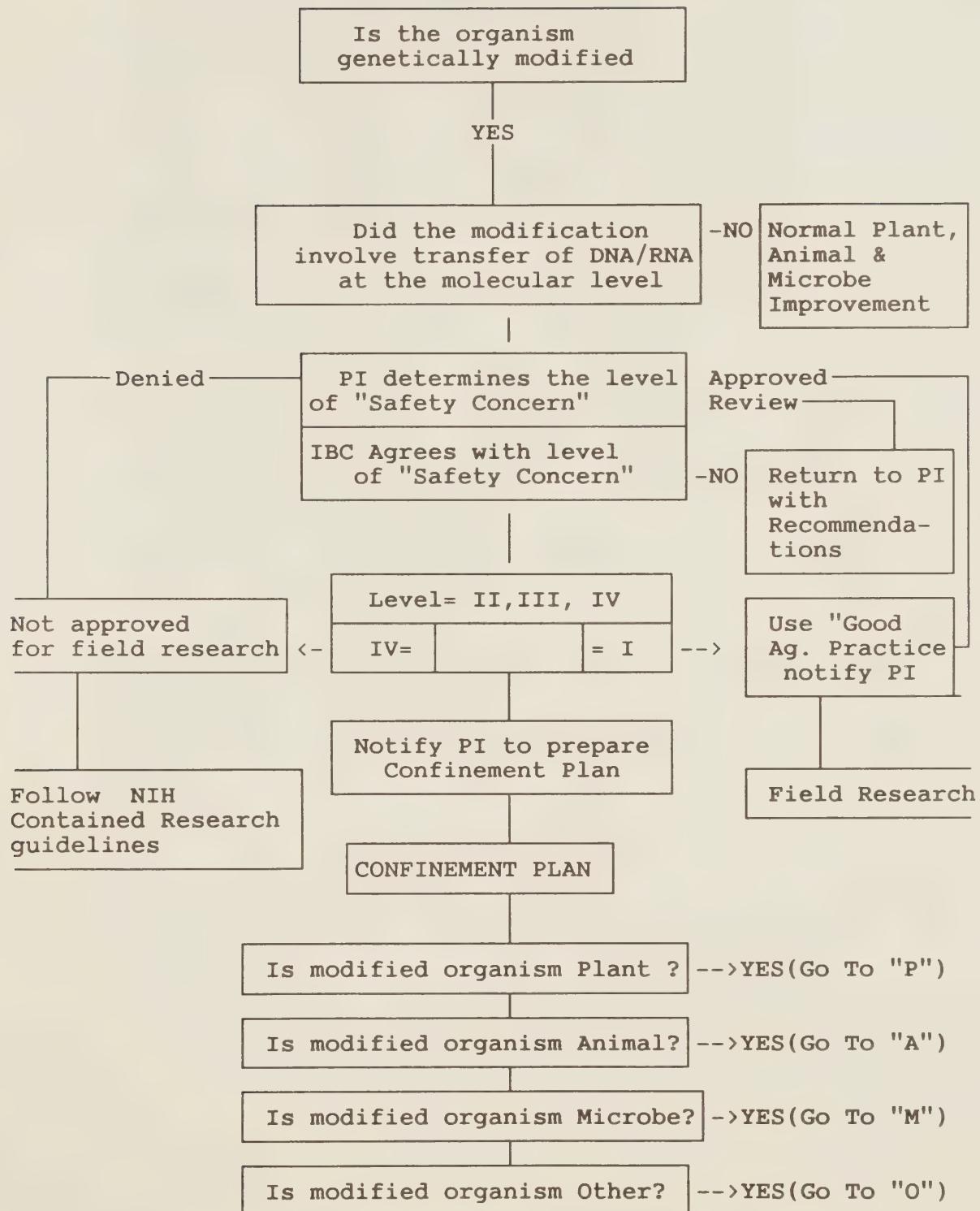
Microorganism - For purposes of these guidelines, a microorganism is defined as any organism or entity capable of reproduction that is not visible to the human eye. This definition includes viruses, viroids, bacteria, protozoa, fungi and certain algae. The definition is operational and encompasses those reproducing entities with which the scientific community and the general public are concerned about their biosafety.

LEE _____

RUDY _____

ANNE _____

SUE _____



"P" (PLANTS)

Weed <--NO Is Plant Domesticated? NO-->Wild or Native

YES

Is Plant Terrestrial? NO-->Aquatic

YES

Is Plant An Annual? NO-->Perennial
|Woody | Herbaceous|

YES

Is Plant seed propagated? NO--> Clonal Plants

YES

"SAFETY LEVEL"

II III IV

SAFETY LEVEL II (Does not hybridize or cross with indigenous plants)

- Contain all plants in plot
- Control movement of seeds and secure
- Control access to birds, small animals and personnel
- Destroy at termination of experiment.
- Monitor for escaped plants or survivors.

SAFETY LEVEL III (Plants hybridizes or crosses with indigenous plants),(Include all level II) and,

- Isolate Plot
- Control Pollen or sterilize
- Monitor with Trap Crops
- Controlled access
- Provide patrolled security
- Provide Security Fence
- Destroy at termination and fumigate plot

SAFETY LEVEL IV (Plants hybridize, outcrosses and contains genes for resistance to herbicides, etc that could be transfer to noxious weeds),(Include, all levels, II and III) and,

- Provide isolation of a least 3 times to greatest distance that natural pollination has been reported to occur, i.e. 3 standard errors.
- Provide berms to contain all runoff.
- Provide 24 hour surveillance during pollen period.
- Provide locked security fences with alarms.
- Exclude with double measures all pollinators or wild animals and insects.
- Monitor pollen collected in the area for genetic markers.
- Use methods of hand pollination and sterilization when possible.
- Monitor site for 2 seasons after termination of experiment for genetic escapes.

"A" (ANIMALS)

```
Is the animal terrestrial? NO--> Aquatic
|                                         animal
Insects <---NO   Is the animal mammal
|                                         or domestic fowl? NO--> Wild fowl
|                                         |
|                                         Is the animal capable
|                                         of transmitting the
|                                         modified genetic trait? NO--> Use "Good
|                                         trait?                                         Ag Practice"
|                                         |
|                                         YES
|                                         Confinement Level
|                                         to prevent unplanned
|                                         reproduction
|                                         Level=II, II, IV
```

CONFINEMENT LEVEL II (Includes "Good Agricultural Practice") and,
Isolate with locked fence.
Clip wings of fowl and band.
Tattoo or eartag animals.
Exclude predators and pests.
Collect and incinerate products(eggs, milk, etc.).
Incinerate all excess animals and necropsy materials at
termination of experiment.

CONFINEMENT LEVEL III (Includes all of II) and,
Double security fence to prevent breaking in or out.
Continuous monitoring
Maximum security
Sexually sterilize animals.
Destroy all animals and residues at termination.

CONFINEMENT LEVEL IV (Includes all of Level III) and,
See new guidelines draft.

"M" (MICROORGANISMS)

Is Microorganisms a non
human or animal pathogen?

NO Pathogen

YES

Is Microorganism plant
pathogen?

YES Plant
Pathogen

NO

Microorganism
Terrestrial?

NO Aquatic

YES

CONFINEMENT LEVEL
II, III OR IV

CONFINE LEVEL II (mostly soil borne, non motile, does not readily exchange genetic information, not vectored by insects, does not form endospores)

Isolate plot.

Prevent exclude animals and pests that can carry soil.

Prevent movement by wind and water.

Fence and exclude people.

Prevent movement by contamination of hands, clothing, shoes.

Disinfect upon entry and exit.

Monitor for movement.

Fumigate soil at termination of experiment.

CONFINEMENT LEVEL III (arboreal and soil colonizers, motile but movement limited, may be vectored by insects, forms endospores, contains toxins for some life forms, evidence for significant exchange of genetic information) all of Level I and,

Exclude vectors and trap and monitor vectors in vicinity.

Double security fence locked.

Patrol area and have procedures if security is breached.

Monitor organisms both inside and outside confinement.

Monitor for exchange in organism reported to have exchanged genetic information.

Record entry and exits from plot.

Fumigate plot at termination and employ techniques to destroy all endospores.

Locate pools or plots in areas where water and plants will not reach natural drains or bodies of water if ruptures or failures occur.

Test system with non modified parents prior to field research to insure integrity of confinement.

Destroy at termination and record number of plants, wet biomass, number of seed, tubers or reproductive organs and the methods used to destroy seeds, tubers, other reproductive organs and plants.

Record number of plants, seeds, tubers or other organs retained for future research.

Monitor plots or pools for 4 years and parent plants for transfer of genetic information.

CONFINEMENT LEVEL IV (arboreal and soil colonizers which are motile and which have been reported to readily exchange genetic information and which form endospores, or other long term methods of survival, produce toxins or other biocides or are readily vectored or spread by insects, wildlife, wind or water) add of Level II and,

Double confinement fences, barriers, and screens and netting.
Twenty four hour surveillance.

Emergency termination and monitoring procedures if security is breached.

Monitor to demonstrate that expected exchange of genetic information has occurred.

Use double deactivation techniques for materials and personnel entering and leaving plot.

Destroy all organisms at termination of experiment and all endospores or other long term survival bodies, and monitor site for 3 years.

"AAF" (FIN FISH)

Is Fish fresh water? NO Marine Fish

YES

Is Fish Non Game? NO Game Fish
YES

CONFINEMENT LEVEL
II, III OR IV

CONFINEMENT LEVEL II(Does not cross or hybridize with related species, is not sexually mature or is chemically or physically made non fertile)

Isolate from any connecting water ways or drains.

Require pumping of all inlet and outlet water so no gravity or natural siphoning can normally occur.

Screen all inlets and outlets to prevent escape.

Have sufficient freeboard to prevent overflow from 100 year storm.

Have sufficient berm design to prevent accidental failure and barriers and liners to prevent burrowing animals from penetration.

Screen and fence and lock to prevent pests, wildlife and trespassers from removal of modified fish.

Mark, brand or otherwise uniquely identify fish.

Have overflow area that can contain 2 times the volume of any catastrophic breach of berms and keep water levels low at all times.

Record the numbers of fish stocked, deaths and removals and number present at termination.

Patrol surveillance and have emergency termination procedure.

Destroy all unneeded fish at termination and report number and identification of those retained for future research.

Monitor wild population of parent stock for presence of modified fish for two years following field research.

CONFINEMENT LEVEL III (Modified fish are sexually mature, can cross or hybridize will large numbers of native specie, or contain genetic material from unrelated animals, plants, or microorganism, or the modification would enhance their competitive advantage with wild forms or increase their nuisance characteristics.) all of II and,

Monitor fish for sexual maturity and spawning.
Collect all drainage water during spawning period, and check for evidence of eggs, fry or milt.
Recycle or retrain all drainage water during spawning period and for two weeks prior to and following spawning.
Biologically deactivate all non recycled drainage water.
Monitor and retrain samples of roe, milt and fry for post experiment analysis.
Determine if crossing and hybridization can occur with native populations and genetic fingerprint of such crosses.
Provide 24 hour surveillance and security.
Record all entry and egress to plots.
Estimate numbers produced.
Destroy all excess fish at termination and incinerate.
Record and uniquely all fish removed or retained for research purposes.

CONFINEMENT LEVEL IV (Modified fish contain genetic information from unrelated organisms, are sexually mature, contain characteristics which are known to increase their competitive advantage, and or nuisance characteristics) all of Level II and III and,

Plots must be isolated, secured, and have 24 hour on site monitoring by trained, qualified personnel.

All drains and inlets must be triple screened and berms and freeboard maintained to exceed by a factor of a 100 year rainfall event.

An emergency termination plan and system must be in place and demonstrated and tested prior to an during the research.

Blind deliberate releases of marked parental fish will be made into the drains and retention system to test the integrity of the retention. Any failure will result in immediate termination.

All fish must be destroyed at the termination of the experiment, except for those to be retained for research purposes which must be clearly marked and have prior notification of intention to retrain. Destroyed fish must be incinerated and verified by a third party.

The site and surroundings must be monitored for 3 years following the termination.

"AP" (AQUATIC PLANTS)

CONFINEMENT LEVEL II(Plants that are not capable of sexual reproduction or cannot cross with indigenous plants)Includes Good Agricultural Research Practice and,

Control and isolate plots or pools.

Prevent movement of plants by wild life, fowl, predators and trespassers.

Prevent loss of plants and plant material through drainage waters.

Clean tools and clothing before leaving plots.

Destroy at termination.

CONFINEMENT LEVEL III(Plants that reproduce by sexual means, that produce pollen, seeds or tubers, and may be weeds or nuisances in the environment)Includes all of Level II and,

Prevent dispersal of pollen, by wind, water, wildlife or insects.

Remove plants from the near environment that can be cross pollinated.

Screen all inlets and outlets to prevent movement of seeds, tubers or other plant parts.

Recycle water when possible.

Maintain catchment basins for drainage waters and pump all outlet water so no gravity drainage or siphoning can occur.

Develop and test plan for emergency termination of experiment if catastrophic breach occurs.

Construct all berms with liners or barriers to prevent burrowing animals from penetrating berms and dams.

Isolate from natural drainage waterways.

Provide patrol surveillance.

Monitor near environment for escapade plants, seeds or pollen.

Monitor parent plants for transfer of genetic information.

Destroy all plants at termination, drain plots or pools, monitor for regrowth, treat or fumigate.

CONFINE LEVEL IV(Plants that both sexually and asexually reproduce, or contain genetic information from non plant sources, and have a high likelihood of adversely affecting the environment, impacting human health or producing toxic materials)Include all Level III and,

Fence and screen plots with double locked fences and/or screens as required.

Maintain free board in all plots or pools to contain water in excess of a 100 year storm.

Provide 24 hour surveillance.

Develop and test a plant to monitor severe weather conditions and secure or terminate if conditions are imminent that could breach confinement and spread the plants.

Inventory plants weekly to estimate number of plants, pollen, seeds or other reproductive organs and maintain all such records.

THE FOLLOWING SCHEME IS PREDICATED UPON THESE ASSUMPTIONS:

1. THE "LEVEL OF SAFETY CONCERN" CAN BE OBJECTIVELY ESTABLISHED.
2. THE "LEVEL OF SAFETY CONCERN" DETERMINES THE CONFINEMENT LEVEL.
3. OVERSIGHT BY (IBC's, OAB, and ABRAC) IS RESPONSIBLE FOR CONFINEMENT ASSURANCES.

Working Document 1 *Confinement*

Appendix 3

TERRESTRIAL PLANTS

	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Isolate Research Site	Distance determined by potential for spread or genetic exchange	Double maximum potential distance for spread or genetic exchange	Triple maximum potential distance for spread or genetic exchange
Control / Monitor	-control seeds and pollen -monitor for escape	-double controls -nighttime monitors	-triple controls -use hand pollination -24 hour monitors -berms to collect runoff
Prevent / Monitor Access	-prevent access	-locked gates -patrols -record people entering and leaving	-double locks -alarms 24 hour patrol
Terminate	-destroy plants at termination	-fumigate site -monitor for one season after research termination	-emergency plan -monitor for two seasons after research termination

TERRESTRIAL ANIMALS

	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Isolate Research Site	isolate and lock site	double lock site	alarm
Control / Monitor Organisms	-monitor for escape -clip wings and band fowl	-current inventory of animals	-equip animals with radio transmitters -utilize berms to collect runoff
Prevent / Monitor Access to Research Site	-prevent access	-record people entering and leaving -patrolled security	-double fence and alarms -controlled access of people -24 hour patrol
Terminate Research	-collect and incinerate products -destroy animals and necropsy materials	-monitor for escape one season after research	-monitor for two seasons after research

AQUATIC PLANTS

	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Isolate Research Site	isolate site	<ul style="list-style-type: none"> -isolate from natural drainage waterways -prevent pollen dispersal by wind, water, and insects -remove plants from accessible environment that can be pollinated 	<ul style="list-style-type: none"> -locate pools or sites where water and plants will not reach natural drains or bodies of water if rupture or failure occurs
Control/ Monitor Organisms	<ul style="list-style-type: none"> -prevent loss through drainage -clean tools and clothing before exit 	<ul style="list-style-type: none"> -screen inlets and outlets -catchment basins for drainage water-pump outlet water so no gravity drainage or syphoning occurs -monitor accessible environment for escaped plants, seeds or pollen 	<ul style="list-style-type: none"> -maintain freeboard or pools to contain water in excess of a 100 year storm -inventory plants weekly to estimate number of plants, pollen, seeds, or other reproductive organs -test system with parental organism prior to research
Prevent/ Monitor Access to Research Site	-prevent access	<ul style="list-style-type: none"> -construct berms with liners or barriers to prevent burrowing animals from penetrating -patrolled security -procedures for breach -record people entering and leaving -locked fence 	<ul style="list-style-type: none"> -fence and screen with double locks -24 hour surveillance

Terminate Research	-destroy organisms	-emergency plan -drain pools, monitor for regrowth, treat or fumigate -monitor parental plants for transfer of genetic information for 2 years	- plan to monitor severe weather conditions -record number of plants, wet biomass, number of seed, tubers, other reproductive organs retained for future research -monitor for 3 years
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AQUATIC ANIMALS

	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Isolate Research Site	isolate pools from connecting waterways or drains	isolate further	isolate further
Control / Monitor Organisms	<ul style="list-style-type: none"> -pump all inlet and outlet water so no gravity or natural syphoning occurs -screen all inlets and outlets -have sufficient freeboard to prevent over flow from 100 year storm -mark, brand, or otherwise uniquely identify animals -have overflow area that can contain 2 times the volume of any catastrophic breach of berms -keep water levels low -record numbers of animals stocked, deaths, and removals and number present at termination -clean tools and clothing before exit 	<ul style="list-style-type: none"> -monitor animals for sexual maturity and spawning -check all drainage water during spawning period for evidence of eggs, fry, larvae, or milt -recycle or retain all drainage water during spawning for two weeks -biologically deactivate all non-recycled drainage water during spawning -estimate numbers of offspring produced 	<ul style="list-style-type: none"> -24 hour on site monitoring -triple screen drains and inlets -maintain freeboard or to exceed by a factor of 2 of a 100 year rainfall event -blind deliberate releases of marked parental animals

Prevent/ Monitor Access to Research Site	-prevent access -patrolled security -sufficient berm design to prevent accidental failure and to prevent burrowing animals from penetration	-procedures for breach -record people entering and leaving -locked fence -24 hour surveillance	-fence and screen with double locks
Terminate Research	-destroy animals -report number and identification of those retained for future research -monitor wild population of parent stock for presence of modified animals for 2 years following research	-monitor and retain samples of roe, milt, and fry for post research analysis	-emergency plan -clearly mark retained animals and have prior notification of intention to retain -verify destroyed animals by a third party -monitor site for 3 years following termination

INSECTS

	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Isolate Research Site	isolate plot	<ul style="list-style-type: none"> -double isolation distance -destroy all insects, hosts, and habitat in site and accessible environment 	<ul style="list-style-type: none"> -increase isolation
Control / Monitor Organisms	<ul style="list-style-type: none"> -control movement -limit number of organisms -monitor trap hosts in accessible environment -beginning and ending inventory 	<ul style="list-style-type: none"> -keep insects confined to research site -prevent movement that will allow crossing or interbreeding with parental insects -monitor for escape 	<ul style="list-style-type: none"> -mark or uniquely identify -estimate by census the number of insects weekly -monitor the accessible environment for escapes with sticky boards and trap hosts
Prevent / Monitor Access to Research Site	-prevent access	<ul style="list-style-type: none"> -patrolled security -plan for breach of security on integrity of confinement -record people entering and leaving -locked security fence 	<ul style="list-style-type: none"> -double screen and fence -double lock entries -24 hour patrol
Terminate Research	<ul style="list-style-type: none"> -destroy organisms, including target host and alternate hosts -burn, fumigate, or otherwise deactivate 	<ul style="list-style-type: none"> -monitor parental insects for two years after research for movement of genetic information 	<ul style="list-style-type: none"> -emergency termination plan -destroy or secure insects if impending weather threatens security -destroy all escaped insects -monitor for 3 years

MICROORGANISMS

	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Isolate Research Site	isolate plot	further	further still
Control / Monitor Organisms	<ul style="list-style-type: none"> -control movement -prevent movement by wind and water -monitor for escaped organisms -disinfect hands, clothing, shoes, and tools upon entry and exit 	<ul style="list-style-type: none"> -exclude vectors -trap and monitor vectors in accessible environment -monitor organisms inside and outside confinement -monitor for exchange in organisms reported to have exchanged genetic information 	<ul style="list-style-type: none"> -monitor to demonstrate that expected exchange of genetic information has occurred -double deactivation techniques for materials and personnel entering and leaving -double locked confinement fences, barriers, and screens and netting
Prevent / Monitor Access to research Site	-prevent access	<ul style="list-style-type: none"> -record people entering and leaving -patrolled security -plan for breach of security -double locked fence 	<ul style="list-style-type: none"> -24 hour surveillance
Terminate Research	-fumigate	<ul style="list-style-type: none"> -destroy all endospores 	<ul style="list-style-type: none"> -emergency plan -monitor site for 3 years

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